K091354
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510(k) Summary

Sponsor:	AcryMed, Inc. 9560 SW Nimbus Avenue Beaverton, OR 97008
Contact Person:	Charles K. Griffin; (503)-624-9830, ext. 280
Device Name	AcryDerm® Silver Antimicrobial Foam Wound Dressing
Common Name:	Hydrophilic Wound Dressing
Classification Product Code:	FRO
Classification Advisory Panel:	General and Plastic Surgery

OCT 21 2009

Legally marketed device(s) for substantial equivalence comparison:

Optifoam® Ag Antimicrobial Foam Dressing (Medtrade Products Ltd, Cheshire UK)
Polymem® Silver (Ferris Mfg. Corp., Burr Ridge IL)
Silver Antimicrobial Wound Gauze (Medline Industries, Mundelein IL)

Description of Device: AcryDerm Silver Antimicrobial Foam Wound Dressings are sterile, single use hydrophilic polyurethane foam dressings containing antimicrobial silver for use in the management of wounds.

Intended use of the Device: AcryDerm Silver Antimicrobial Foam Wound Dressings are indicated for the management of 1st and 2nd degree burns, wounds such as venous and arterial ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

Technological Characteristics: The AcryDerm Silver Foam Antimicrobial Wound Dressings incorporate a combination of silver saccharinate salt and a metallic silver as stabilized reservoirs for generating antimicrobial ionic silver upon contact with aqueous moisture such as would be commonly encountered when used as a wound dressing on dermal surfaces and exuding wounds. The antimicrobial components are incorporated in the dressing matrix which is composed of a hydrophilic polyurethane foam which acts to help control the moisture level in the wound.

Testing: the new product meets or exceeds safety and biocompatibility assurance guidelines as provided in the guidance of Part-1 of the ANSI/AAMI/ISO standard (10993-1:2003 - *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing*)

Manufacturing: The new silver antimicrobial foam dressing product will be manufactured according to the product specifications and in accordance with good manufacturing practices to ensure the device is safe and effective for the intended use.

Performance Standards: No performance standards are prescribed for the new product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

AcryMed, Inc.
% Mr. Charles K. Griffin
9560 SW Nimbus Avenue
82 Cambridge Street
Beaverton, Oregon 97008

OCT 21 2009

Re: K091354
Trade/Device Name: AcryDerm Silver Antimicrobial Foam Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 8, 2009
Received: September 15, 2009

Dear Mr. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091354

Device Name: AcryDerm Silver Antimicrobial Foam Wound Dressing

Indications for Use:
AcryDerm Silver Antimicrobial Foam Wound Dressing is indicated for the management of 1st and 2nd degree burns, wounds such as venous and arterial ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091354